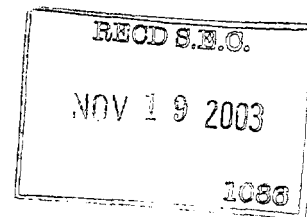


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Basel, 13 November 2003

## Phase III Trial of MabThera for Maintenance Treatment of Indolent non-Hodgkin's lymphoma (NHL) Halted Early Due to Significant Efficacy Benefits

Roche, Genentech, Inc., and Biogen Idec have been informed that a US Eastern Cooperative Oncology Group (ECOG) Phase III study (E1496) evaluating MabThera (rituximab) maintenance therapy in indolent NHL has met its pre-specified primary efficacy endpoint earlier than expected. A pre-planned interim analysis of the study data by an independent ECOG Data Monitoring Committee (DMC) demonstrated a statistically significant improvement in time to treatment failure for patients receiving MabThera maintenance therapy. Based on this analysis, the DMC has stopped further randomisation of patients on this study.

"The positive outcome of this study is extremely encouraging and provides additional evidence that MabThera may significantly change the disease course of indolent NHL," said William M. Burns, Head of Roche Pharmaceuticals Division.

"This is excellent news for patients with indolent NHL. This decision by the committee suggests that an entirely new treatment concept is on the horizon – the maintenance of the benefits of induction therapy – which until now has not been standard practice," said Dr. Stefan Manth, Head of Roche Oncology.

The Phase III study enrolled previously-untreated patients with indolent NHL. All patients received a maximum of eight doses of induction therapy with cyclophosphamide, vincristine, and prednisone (CVP). At the time that the study was stopped, 322 patients who responded or had stable disease following induction CVP chemotherapy had been randomised to receive either MabThera maintenance therapy or no further treatment. MabThera maintenance therapy consisted of four weekly doses of MabThera every six months for two years. In this study, time to treatment

failure was evaluated as the time from randomisation to the first failure, defined as documented disease progression or death.

#### **About MabThera**

MabThera is a therapeutic antibody that binds to a particular protein - the CD20 antigen - on the surface of normal and malignant B-cells. It then recruits the body's natural defences to attack and kill the marked B-cells. Stem cells (B-cell progenitors) in bone marrow lack the CD20 antigen, allowing healthy B-cells to regenerate after treatment and return to normal levels within several months.

MabThera is indicated as a single-agent treatment for relapsed or refractory low-grade or follicular, CD20 positive, B-cell NHL and received European approval in March 2002 for the treatment of aggressive NHL in combination with CHOP chemotherapy. MabThera is referred to as Rituxan in the United States, Japan and Canada. More than 300,000 patients have been treated with MabThera worldwide.

Genentech and BiogenIdec co-market MabThera in the United States, Roche markets MabThera in the rest of the world, except Japan where MabThera is co-marketed by Chugai and Zenyaku Kogyo Co. Ltd.

#### **About ECOG**

The Eastern Cooperative Oncology Group (ECOG) was established in 1955 as one of the first cooperative groups launched to perform multi-centre cancer clinical trials. A cooperative group is a large network of researchers, physicians, and health care professionals at public and private institutions across the country who are members of the group. Funded primarily by the National Cancer Institute (NCI), ECOG has evolved from a five member consortium of institutions on the East Coast to one of the largest clinical cancer research organizations in the United States with almost 6,000 physicians, nurses, pharmacists, statisticians, and clinical research associates (CRAs) from the United States, Canada, and South Africa.

#### **About Roche**

Headquartered in Basel, Switzerland, Roche is one of the world's leading innovation-driven healthcare groups. Its core businesses are pharmaceuticals and diagnostics. Roche is number one in the global diagnostics market and is the leading supplier of pharmaceuticals for cancer and a leader in virology and transplantation. As a supplier of products and services for the prevention, diagnosis and treatment of disease, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche employs roughly 65,000 people in 150 countries. The Group has

alliances and research and development agreements with numerous partners, including majority ownership interests in Genentech and Chugai.

#### **About Genentech**

Genentech is a leading biotechnology company that discovers, develops, manufactures and commercializes biotherapeutics for significant unmet medical needs. Sixteen of the currently approved biotechnology products originated from or are based on Genentech science. Genentech manufactures and commercializes 12 biotechnology products in the United States. The company has headquarters in South San Francisco, California and is traded on the New York Stock Exchange under the symbol DNA.

#### **About Biogen Idec**

Biogen Idec creates new standards of care in oncology and immunology. As a global leader in the development, manufacturing, and commercialization of novel therapies, Biogen Idec transforms scientific discoveries into advances in human healthcare. For product labelling, press releases and additional information about the company, please visit [www.biogenidec.com](http://www.biogenidec.com).

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